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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,582	01/30/2004	Niall Duffy	009.1012 (P1701)	8576

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EXAMINER	
APANIUS, MICHAEL	
ART UNIT	**PAPER NUMBER**
3736	

NOTIFICATION DATE	DELIVERY MODE
06/22/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/769,582	DUFFY, NIALL	
	Examiner	Art Unit	
	Michael Apanius	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *13-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/18/2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 4/2/2007 is acknowledged. Claims 13-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. It is noted that claims 20-24 were part of Group I as set forth in the restriction requirement mailed 3/27/2007.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 20-24 rejected under 35 U.S.C. 102(e) as being anticipated by Armstrong et al. (US 2004/0193139). Armstrong discloses a catheter having a single stable and undeformed configuration, comprising:

an elongate shaft (15) having an exterior surface, a proximal end, and a distal end;

a first lumen (around 19 in figure 1F) extending through the shaft from the shaft proximal end to the shaft distal end (paragraph 15, lines 3-4) when the catheter is in the single stable and undeformed configuration, and sized to receive a guidewire (19); and

a guideway (at the top of 104) extending from the shaft proximal end to the shaft distal end (paragraph 15, lines 3-4) when the catheter is in the single stable and undeformed configuration, and enabling transverse access from the shaft exterior surface to the first lumen.

4. In regards to claim 21, the shaft further comprises a second lumen (22) extending through the shaft from the shaft proximal end to the shaft distal end, and having a nearly annular cross sectional area that almost entirely surrounds the first lumen (see figures 1F-1H). In regards to claim 22, the first lumen and the second lumen are both formed from a single wall having a substantially uniform thickness. In regards to claim 23, the single wall includes two approximately parallel segments that together define the catheter guideway. In regards to claim 24, the two parallel segments are adapted to be flexibly spaced apart (as is required to remove the guidewire from the slot 104).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armstrong et al. (US 2004/0193139) in view of Greelis et al. (US 5,346,498).

7. Armstrong discloses a catheter as noted above but does not expressly disclose a catheter advancing and retracting apparatus as set forth in claims 1 and 6-11.

8. Greelis discloses an apparatus for advancing and retracting elongated, flexible medical instruments, such as a catheter and a guidewire (column 8, lines 1-4), in a patient, the apparatus comprising: an elongate housing (61 in figure 2) having a proximal end and a distal end; an opening (through 59 and 73) formed through the housing from the proximal end to the distal end and adapted to house elongated, flexible medical instruments; a wheel port (figure 11) formed in the housing between the proximal and distal ends and in communication with the opening; and a wheel (83C in figure 11) secured in the wheel port and radially extending into the opening to engage with an elongated, flexible instrument. In regards to claim 6, the wheel port includes slots (93C), and the wheel includes an axle (91C) that is rotatably secured in the slots. In regards to claim 7, the wheel includes a large diameter portion (the portion comprising the two upward facing regions (209, 215) and the portion there between as shown in figure 12) and two small diameter portions (the portions on each side of the large diameter portion) flanking the large diameter portion. In regards to claim 8, the large diameter portion has a circumferential concave surface (103C). In regards to claim 9, each of the small diameter portions has a circumferential concave surface (213 and the notch portion on the left). In regards to claim 10, the large diameter portion is approximately centered between the small diameter portions. In regards to claim 11,

wheel port is formed proximate to the housing distal end. Greelis teaches the catheter advancing and retracting apparatus for the purpose of simplifying catheter positioning (column 2, lines 23-25) and to allow single-handed operation (column 2, lines 44-48). Note that the wheel of Greelis is sized to extend into a flexible catheter guideway.

9. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the catheter advancing and retracting apparatus as taught by Greelis with the catheter of Armstrong in order to simplify catheter positioning and to allow single-handed operation.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Armstrong et al. (US 2004/0193139) as modified Greelis et al. (US 5,346,498) as applied to claims 1-11 above, and further in view of Horzewski et al. (US 5,364,376). Armstrong as modified by Greelis discloses a catheter guiding assembly as noted above. However, Armstrong as modified by Greelis does not appear to disclose a guidewire removal tool as set forth in claim 12. Horzewski teaches a guidewire removal tool (24) have a substantially cylindrical main body sized to be received in a guidewire lumen and having a chamfered leading edge (26) adapted to raise the guidewire out of the lumen for the purpose of facilitating guidewire exit when the catheter is threaded over the guidewire (coluimn 2, lines 3-6). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a guidewire removal tool as taught by Horzewski in the assembly of Armstrong as modified by Greelis in order to facilitate guidewire exit when the catheter is threaded over the guidewire.

Response to Arguments

11. Applicant's arguments with respect to the previous prior art rejections have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA